Diabetes Subcommittee meeting held 11 July 2011

(minutes for web publishing)

The Diabetes Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Diabetes Subcommittee meeting; only the relevant portions of the minutes relating to Diabetes Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are published.

The Diabetes Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 11 & 12 August 2011, the record of which is available on the PHARMAC website.

Contents

1 Special Authority criteria for Insulin Pumps

1.1 The Subcommittee considered the recommendation made by PTAC which was for the Subcommittee to come up with suitable eligibility criteria for access to funded insulin pumps and consumables following its meeting on 6 May 2011.

1.2 The Subcommittee **recommended** that the criteria for nocturnal hypoglycaemia should read 'severe, unexplained, recurrent nocturnal hypoglycaemia' and that the criteria for hypoglycaemia should read 'severe, unexplained, recurrent hypoglycaemia requiring assistance'.

1.3 The Subcommittee noted that defining a threshold HbA1c level for access to insulin pumps would be inappropriate and that this may not only encourage patients to raise their HbA1c levels in order to meet the criteria, but may exclude a proportion of patients who would benefit from using an insulin pump.

1.4 The Subcommittee noted that the approval period for the initial subsidy of insulin pump consumables was 9 months, and that this would represent a reasonable timeframe for a trial period. The Subcommittee considered that a renewal period for consumables of every two years was appropriate and that patients should be re-evaluated for suitability to remain on a funded pump with this frequency.

1.5 The Subcommittee noted that the draft criteria would target patients who have type 1 diabetes and who have been using multiple daily injections of an insulin regimen containing analogue insulins. The Subcommittee considered whether the criteria would target newly diagnosed paediatric patients who had not trialled a multiple daily injection regimen and who may benefit from using an insulin pump. Members noted that most paediatric patients would be initiated on MDI. Members noted that newly diagnosed adult patients would not require an insulin pump on diagnosis without first using MDI.

1.6 The Subcommittee considered the approach to assessing patients who are currently receiving funded pumps and/or consumables through their DHB. The Subcommittee noted that many patients are benefiting from pump therapy and that they should be eligible to continue to receive funded access. The Subcommittee noted that patients who have self funded pumps and consumables would need to meet the new eligibility criteria for funded access, or have meet them at the time of initiation of pump therapy. The Subcommittee **recommended** that existing pump treated patients should have an application, based on their medical history prior to and post pump therapy, assessed by a panel for their eligibility to gain subsidised access.

1.7 The Subcommittee considered the special authority renewal criteria for insulin pumps and consumables. Members noted that the assessment benefit from using an insulin pump should be measured against the criteria for which the user was initially eligible and noted that stable or better HbA1c levels and a stabilisation or reduction in the frequency of diabetic hypoglycaemic/ketoacidotic events should be considered also.

1.8 The Subcommittee considered whether microvascular complications could be used in the eligibility criteria. Measures of retinopathy and microalbuminuria could be used to target

patients with more advanced diabetes, and could be used as measures in the renewal assessment. Members also noted however that ideally pump treatment would be used before the development of microvascular complications with the aim of preventing them.

1.9 The Subcommittee noted that insulin pumps should only be offered by DHBs that have multidisciplinary diabetic teams which include a diabetes physician or endocrinologist trained and experienced in insulin pump therapy and DHBs who do not offer this would need to refer patients to a larger service for initiation.

1.10 The Subcommittee noted that funding of insulin pumps and consumables would require intensive nurse and clinician time. Members noted that there would be capacity limitations which would be a rate limiting step for access in some DHBs. It noted that paediatric patients are usually trained individually while adult patients are often trained in groups and therefore require different levels of resource allocation. The Subcommittee noted the forecast for the number of patients accessing funded treatment in the model could be high for this reason.

1.11 The Subcommittee considered whether the criteria would limit access by pre-gestational women. Members noted that pre-gestational women with type 1 diabetes would be eligible under the proposed criteria if they did not achieve target HbA1C levels despite optimum MDI therapy. Members noted that this patient group would be eligible for renewal if they maintained improvement in HbA1C following pregnancy.

1.12 The Subcommittee further considered the formation of a panel composed of clinicians experienced in the use of insulin pumps. As well as deciding on applications from patients with pumps funded under previous regimes, this panel would consider access for patients with exceptional circumstances, and renewals for patients in whom the benefit of pump therapy was difficult to assess.

1.13 The Subcommittee considered that in the event that pumps were funded, it would be useful to establish a database which collated clinical information such as HbA1c levels, number of severe hypoglycaemic or diabetic ketoacidotic episodes, number of hospital admissions, microvascular complications and deaths. An audit of this data could help to inform us about the safety of insulin pumps and the future eligibility criteria and funding for insulin pumps.

1.14 The Subcommittee proposed the following Special Authority:

Special Authority for Subsidy for insulin pump

Initial application only from a relevant specialist. Approvals valid for three months for applications meeting the following criteria:

1. Patient has type 1 diabetes; and
   - 1.1. has adhered to an intensive MDI regimen using analogue insulins for at least three months but still has either
     - 1.1.1. severe unexplained recurrent nocturnal hypoglycaemia; or
     - 1.1.2. severe unexplained recurrent hypoglycaemia requiring assistance; or
     - 1.1.3. chronically raised HbA1c despite optimal MDI therapy; or
   - 1.2. is a child and in the opinion of the treating specialist a trial with a MDI regimen would be unsuitable and inappropriate; or
   - 1.3. is already on pump treatment and before date x met the above eligibility criteria for funded pumps and/or consumables and continues to benefit from pump treatment; and

1.4. has undertaken a carbohydrate counting course, and
1.5. has been evaluated for psychological suitability for a pump, and

2. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care;

Renewal only from a relevant specialist. Approvals valid for three months for applications meeting the following criteria:

1. Patient is continuing to derive benefit due to reduced hypoglycaemic events or maintaining similar or better glycaemic control (HbA1c is less than or similar to pre-initiation HbA1c);
2. It has been at least 4 years since the last insulin pump received by the patient or in the case of patients qualifying under 1.5 the pump is due for replacement.

Special Authority for Subsidy for insulin pump consumables

Initial application only from a relevant specialist. Approvals valid for nine months for applications meeting the following criteria:

1. Patient has had a Special Authority for an insulin pump approved under SA xxx

Renewal only from a relevant specialist. Approvals valid for two years for applications meeting the following criteria:

Patient is continuing to derive benefit from insulin pump therapy as defined by:

1. stabilisation or reduction of hypoglycaemic events compared with pre-pump frequency; and/or
2. is maintaining better glycaemic control (HbA1c is stable **or** less than pre-initiation HbA1c); and
3. the patient continues to be part of a multidisciplinary team experienced in type I diabetes care; and
4. the patient continues to be compliant.